UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,035	02/24/2004	John N. Voumakis	7867-052-999	3906

20583 7590 08/12/2005

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/787,035	VOURNAKIS ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *12-14,16 and 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,15,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21 are pending. Claims 1-11, 15, 17, 18 are considered on the merits. Claims 12-14, 16, 19-21 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 12-14, 16, 19-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made without traverse in Paper No. 6/20/05.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 3, 5-11, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 merely recites that the composition has 50% fiber slurry, but fails to state how much polymer is in the slurry. Thus, the metes and bounds of the claim cannot be determined. Concentrations of slurry require disclosure of the amount by weight or volume per weight or volume of mixture.

Claim 5 recites "at least 0.125% $CaCl_2$ solution.". However, the claim does not describe how the % is calculated. For example, is it weight/volume, volume/volume weight/weight. Use of % alone without definition numerator and denominator is always indefinite.

Likewise, claims 6-9 and 18 also contain "%" without definition of denominator and numerator.

Claim 7 recites that the composition includes magnesium. Magnesium is a metal. It is unlikely that applicants have a chunk of magnesium metal in their aqueous composition. Please insert "ions" and be careful with the concentration limitations. A solution of 10%w/v magnesium chloride, for

example, does not have the same amount of magnesium ions as a 10% w/v solution of magnesium ion.

Claim 18 recites "in the presence of a 10% calcium chloride solution". However it is doubtful that there is 10g/100 ml calcium chloride in the final composition of the gel.

In order for compositions, which have limitations directed to concentration of components, to be definite, the concentration of each component in the total composition should be clearly set forth. Concentration is defined as amount per volume of the total composition or amount per weight of the total composition. For example, please try to clarify how much calcium chloride is in the final composition (mg or moles of calcium chloride/ml of mixture of PRP and fiber). How much p-NAG fiber, NaCl and PRP are in the final mixture in claim 8 or 9 or 18 The concentration limitations of the components are completely uninterpretable and, therefore, cannot be considered as further limiting the claimed compositions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Okamoto *et al.* [U] in light of US 4,663,289 [A] and US 5,292,524 [D].

The claims are directed to a composition comprising purified poly N-acetylglucosamine polymer and platelets in plasma (PRP). Dependent claims refer to p-NAG polymer 'fiber", without any definition of 'fiber'. Since p-NAG is a polymer, and a polymer is a chain of similar molecules, they can be said to be a 'fiber' or a thread-like structure in the absence of any length limitations.

With regard to the inclusion of calcium chloride in the solution, plasma inherently contains calcium ions and chloride ions as well as magnesium ions. Therefore in the absence of interpretable concentration limitations, the presence of these ions in plasma of platelet-rich-plasma preparations meets the limitations of the claims.

The references are relied upon as explained below.

Okamoto *et al.* disclose a composition comprising chitin (purified poly N-acetylglucosamine) in PBS and platelets in plasma (PRP), see Table 1 and Material and Methods, page 644. Because the claimed concentration limitations are indefinite, the reference is considered to meet the limitations as plasma contains calcium, magnesium and chloride ions. Further, in claim 18, isolated platelets are mixed with p-NAG and calcium chloride. Okamoto et al. disclose the mixing of isolated platelets with chitin and modified Tyrode's buffer which contains 0.14g/l calcium chloride.

US 4,663,289 in Table 1, shows the concentrations of calcium ion, magnesium ion and chloride ion in plasma in mmoles/L.

US 5,292,524 disclose that Modified Tyrode's Buffer contains 0.14 g/l calcium chloride (col. 16, l. 68).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto *et al.* [U] or US 5,614,204 [B] in combination with US 5,858,350 [C] in light of US 5,292,524 [D] and US 4,663,289 [A].

The claims are directed to a method for accelerating wound healing comprising administering to a wound a composition comprising PRP, p-NAG fiber, wherein the PRP is derived from stored platelets.

The references are relied upon as explained below.

Okamoto *et al.* teach that in early wound healing, blood coagulation plays a very important role because some cytokines are released by platelets during coagulation (Introduction). It is demonstrated that chitin aggregates platelets and subsequently enhances the release of cytokines from platelets (Conclusion). Also disclosed is the composition comprising PRP and chitin, which comprises p-NAG. Plasma inherently contains calcium, chloride, and magnesium ions in certain concentrations as disclosed by US 4,663,289 in Table 1.

US 5,614,204 disclose a composition comprising chitin (col. 12, l. 32) and PRP (col. 12, l. 52) used to induce vascular haemostatic occlusion (clotting). The polymer (chitin) is placed in plasma and added to PRP (col. 13, l. 30).

The references lack the disclosure of the use of p-NAGlucosamine obtained from microalgae which may have distinct characteristics from p-NAGlucosamine obtained from crustacean shell (chitin).

US 5,858,350 discloses pure poly-β,1-4-N-acetylglucosamine derived from microalgae. The references also discloses that chitin which is a β,1-4-N-acetylglucosamine polymer derived from crustacean shells is not 100% pure β,1-4-N-acetylglucosamine and use of chitin gives rise to unpredictable results because of the impurities (col. 1 and 2). Thus, this reference teaches the desirability of the use of pure β,1,4-N-acetylglucosamine derived from microalgae in place of β,1-4-N-acetylglucosamine derived from crustacean

shells. Microalgae produce fibers of various lengths of β,1-4-N-acetylglucosamine.

US 5,292,524 discloses that Modified Tyrode's Buffer has 0.14g/l calcium chloride (col. 16, l. 68).

US 4,663,289 disclose that plasma contains calcium, magnesium and chloride ions (Table 1).

The substitution of a purified form of β,1-4-N-acetylglucosamine polymer from microalgae for the impure form of β,1-4-N-acetylglucosamine polymer in chitin in the compositions of Okamoto *et al.* or US 5,614,204 would have been obvious when taken with US 5,858,350 which teaches the advantages of such a substitution.

The substitution of the purified form of β,1-4-N-acetylglucosamine polymer from microalgae for the chitin in the method of Okamoto *et al.* for producing a platelet gel would have been obvious when the primary reference of Okamoto *et al.* (Preparation of washed platelet, page 644) was taken with US 5,858,350 which teaches the advantages of using such a purified form of β,1-4-N-acetylglucosamine polymer from microalgae. Please note that Modified Tyrode's Buffer used in Okamoto *et al.* for suspension of platelets has 0.14g/l calcium chloride as disclosed by US '524.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651
July 26, 2005